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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/765,476 | 01/18/2001 | Irina A. Buhimschi | BUH385-00/01003A | 9887 |

7590 10/07/2003
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EXAMINER

SNEDDEN, SHERIDAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

DATE MAILED: 10/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,476

Applicant(s)

BUHIMSCHI ET AL.

Examiner

Sheridan K Snedden

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 10 and 20-22 is/are allowed.
- 6) ☐ Claim(s) 1-5, 7-9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper #13, filed 24 June 2003. Claim 19 has been canceled. Applicant's amendment of claims 1-3, 7-9, 12-13 and 18 is acknowledged. Claims 6, 10, 11, and 20-22 are rejoined. Claims 1-18 and 20-22 are under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Information Disclosure Statement

3. Applicant is advised that additional sheets of the PTO-1449 of Paper No: 7, filed 7/2/02 appear to be missing from the application. Additional sheets of PTO-1449 would be considered upon resubmission and required for consideration of all submitted references.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5, 7-9, 12-14, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Coutssoudis *et al.* (AIDS. 1999 Aug 20;13(12):1517-24). Coutssoudis *et al.* teach that the provitamin A, or Beta-carotene, supplementation has the potential for reducing the incidence of preterm

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births. The supplementation was given to women likely to suffer from pre-term labor. Thus, the reference anticipates the claimed invention.

6. Claims 1, 5, 7-9, 12-14, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Cherouny *et al.* (AIDS 1999 Aug 20;13(12):1517-24). Cherouny *et al.* teach the antioxidants can inhibit contractile activity that resulted from the presence of hydrogen peroxide. Cherouny *et al.* suggests that antioxidants may be a possible treatment against uterine contractions caused by reactive oxygen in preterm labor cause induce by infection. Thus, the reference anticipates the claimed invention.

7. Claims 1, 5, 7-9, 12-14, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrett *et al.* (Int J Vitam Nutr Res. 1994;64(3):192-7). Barrett *et al.* teach the potential role of the antioxidants ascorbic acid (vitamin C) and beta-carotene in the prevention of preterm rupture of fetal membranes. Thus, the reference anticipates the claimed invention.

8. Claims 1, 3, 5, 7-9, 12-14, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese patent 60197669. Japanese patent 60197669 teaches the use of a substance that contains tocopherol (vitamin E), an antioxidant), effective for the remedy of premature labor. Thus, the reference anticipates the claimed invention.

9. Claims 1, 4, 7-8, 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Buhimschi *et al.* (1999). Buhimschi *et al.* (1999) teach that superoxide dismutase and N-acetyl

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cysteine reduce the collagenolytic activity of metalloproteases that are associated with membrane rupture at term and preterm labor. Buhimschi *et al.* suggest that thiol reducing agents may be beneficial in preventing preterm labor. Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 2, 4, 5, 7-9, 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buhimschi *et al.* (1999) in view of Cherouny *et al.*. Buhimschi *et al.* (1999) teach that superoxide dismutase and N-acetyl cysteine reduce the collagenolytic activity of metalloproteases that are associated with membrane rupture at term and preterm labor. Buhimschi *et al.* suggest that thiol reducing agents may be beneficial in preventing preterm labor. Buhimschi *et al.* does not teach the use of an antibiotic.

Cherouny *et al.* teach the antioxidants can inhibit contractile activity that resulted from the presence of hydrogen peroxide. Cherouny *et al.* suggests that antioxidants may be a possible treatment against uterine contractions caused by reactive oxygen in preterm labor induced by infection.

It would have been obvious to combine an antioxidant and an antibiotic for the treatment of preterm labor cause induced by infection. A person of ordinary skill in the art would have been

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motivated to administer the combination treatment to reduce infection, reduce uterine contractions and the rupture of membranes. The person of ordinary skill in the art would have expected success because the administration of antioxidants and antibiotics for the treatment of preterm labor is well known in the art. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

11. Claims 6, 10, 20, 21 and 22 are in condition for allowance.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
October 6, 2003

SKS


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800